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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/762,873	01/21/2004	Nicholas M. Valiante	PP20203.003	5927

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EXAMINER

CHONG, YONG SOO

ART UNIT	PAPER NUMBER
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1617

DATE MAILED: 07/13/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/762,873	Applicant(s) VALIANTE, NICHOLAS M.	
	Examiner Yong S. Chong	Art Unit 1617	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-31 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☐ Claim(s) ____ is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☒ Claim(s) 1-31 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. ____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|--|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date ____ | 6) <input type="checkbox"/> Other: ____ |

DETAILED ACTION

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 1, 2 (in part), 3, 6 (in part), 7-9, 11 (in part) are drawn to method of enhancing an immune response with an antigen derived from bacterial pathogens and tryptanthrin of formula I, classified in class/subclass 424/184.1.
- II. Claims 1, 2 (in part), 5, 6 (in part), 7-9, 11 (in part) are drawn to method of enhancing an immune response with an antigen derived from parasitic pathogens and tryptanthrin of formula I, classified in class/subclass 424/184.1.
- III. Claims 1, 2 (in part), 4, 6 (in part), 7-9, 11 (in part) are drawn to method of enhancing an immune response with an antigen derived from viral pathogens and tryptanthrin of formula I, classified in class/subclass 424/184.1.
- IV. Claims 1, 2 (in part), 6 (in part), 7-9, 11 (in part) are drawn to method of enhancing an immune response with an antigen derived from fungal pathogens and tryptanthrin of formula I, classified in class/subclass 424/184.1.
- V. Claims 1, 2 (in part), 3, 6 (in part), 7, 10, 11 (in part) are drawn to method of enhancing an immune response with an antigen derived from bacterial

pathogens and tryptanthrin of formula II, classified in class/subclass
424/184.1.

VI. Claims 1, 2 (in part), 5, 6 (in part), 7, 10, 11 (in part) are drawn to method of enhancing an immune response with an antigen derived from parasitic pathogens and tryptanthrin of formula II, classified in class/subclass 424/184.1.

VII. Claims 1, 2 (in part), 4, 6 (in part), 7, 10, 11 (in part) are drawn to method of enhancing an immune response with an antigen derived from viral pathogens and tryptanthrin of formula II, classified in class/subclass 424/184.1.

VIII. Claims 1, 2 (in part), 6 (in part), 7, 10, 11 (in part) are drawn to method of enhancing an immune response with an antigen derived from fungal pathogens and tryptanthrin of formula II, classified in class/subclass 424/184.1.

IX. Claims 12-17, 19 (in part) are drawn to a pharmaceutical composition comprising an antigen and a tryptanthrin of formula I, classified in class/subclass 514/250.

X. Claims 12-15, 18, 19 (in part) are drawn to a pharmaceutical composition comprising an antigen and a tryptanthrin of formula II, classified in class/subclass 514/250.

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- XI. Claims 20-22 are drawn to a method of immunotherapy for the treatment of cancer with a tryptanthrin of formula II, classified in class/subclass 514/250.
- XII. Claims 23-30 are drawn to kit comprising tryptanthrin of formula I, classified in class/subclass 514/250.
- XIII. Claim 31 is drawn to small molecule potentiating compound, classified in class/subclass 514/250.

The inventions are distinct, each from the other because of the following reasons:

Inventions IX, X and I, II, III, IV, V, VI, VII, VIII, XI are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case, the method of enhancing immune response can be practiced by drinking orange juice, and the method of treating cancer can be practiced by administering radiation therapy.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, restriction for examination purposes as indicated is proper. Because these inventions are distinct for the reasons given above and the search required for Invention IX, X is not required for Inventions I, II, III, IV, V, VI, VII, VIII, XI, restriction for examination purposes as indicated is proper. A search in the non-patent literature for compositions comprising

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antigens and tryptanthrin derivatives will not necessarily lead to the method of enhancing immune response and treating cancer.

Inventions XII and IX, X, XIII are related as combination and subcombination. Inventions in this relationship are distinct if it can be shown that (1) the combination as claimed does not require the particulars of the subcombination as claimed for patentability, and (2) that the subcombination has utility by itself or in other combinations (MPEP § 806.05(c)). In the instant case, the combination as claimed does not require the particulars of the subcombination as claimed because syringes, nasal inhaler, and a transdermal patch are all patentable matter. The subcombination has separate utility such as anti-inflammatory drugs.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, restriction for examination purposes as indicated is proper. Because these inventions are distinct for the reasons given above and the search required for Invention XII is not required for Inventions IX, X, XIII restriction for examination purposes as indicated is proper. A search in the non-patent literature for tryptanthrin compounds will not lead to compositions comprising antigens and tryptanthrin derivatives and also will not lead to a kit comprising an antigen and tryptanthrin in a separate compartment along with a delivery device.

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Species Election

Claims 1-31 are generic to a plurality of disclosed patentably distinct species. Applicant is required under 35 U.S.C. 121 to elect a single disclosed species, even though this requirement is traversed.

The species are as follows:

- 1) a single disclosed tryptanthrin compound, for example 8-nitroindolo[2,1-b]quinazoline-6,12-dione
- 2) a single disclosed small molecule immune potentiating compound, for example 2,4-dibromo-8-iodoindolo[2,1-b]quinazoline-6,12-dione

If applicants elects inventions I, II, III, IV, V, VI, VII, VIII, IX, X, XI, XII, applicant is further required to elect a single disclosed tryptanthrin compound from subsection 1. Currently, claims 1-30 are generic to a tryptanthrin compound.

If applicant elects inventions XIII, applicant is further required to elect a single disclosed small molecule immune potentiating compound from subsection 2. Currently, claim 31 is generic to a small molecule immune potentiating compound.

Note the court in *In re Herrick et al.* and *In re Joyce et al.* (both at 115 USPQ 412) held that an election of species requirement was, in fact, a restriction requirement.

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over

the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

A telephone call to the attorney is not required where: 1) the restriction requirement is complex, 2) the application is being prosecuted pro se, or 3) the examiner knows from past experience that a telephone election will not be made (MPEP § 812.01). Therefore, since this restriction requirement is considered complex, a call to the attorney for telephone election was not made.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Yong S. Chong whose telephone number is (571)-272-8513. The examiner can normally be reached on M-F, 9-6.

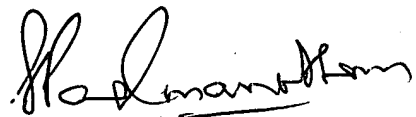
If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, SREENI PADMANABHAN can be reached on (571)-272-0629. The fax

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phone number for the organization where this application or proceeding is assigned is (571)-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

YSC



SREENI PADMANABHAN
SUPERVISORY PATENT EXAMINER